ORTHOPEDICS

510(k) Summary

MAY 18 2012

Preparation Date: 28 October, 2011

Applicant/Sponsor:
Biomet Manufacturing Corp.
56 East Bell Drive
P.O. Box 587
Warsaw, Indiana 46581-0587
FDA Registration Number: 1825034

Contact Person:
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Senior Regulatory Specialist
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Proprietary Name: Metal-On-Metal Hip Systems – Additional Contraindications

Common Name: Metal-on-Metal Hip prosthesis

Classification Name: KWA (888.3330), Hip joint metal/metal semi-constrained, with uncemented acetabular component prosthesis (888.3330)

LPH (888.3358), Hip joint metal/polymer/metal semi-constrained, porous-coated uncemented prosthesis.

Legally Marketed Devices To Which Substantial Equivalence Is Claimed:

K993438 – Metal-On-Metal Acetabular Component
K002379 – M2a Ringloc Acetabular Liner
K011110 – M2a Acetabular System
K042037 – M2a Magnum System
K042841 – M2a / C2a Acetabular System
K061423 – M2a Magnum 12/14 Taper Inserts and One-Piece Modular Heads
K062995 – M2a Magnum Tri-Spike Acetabular Component
K082446 – Biomet Metal-On-Metal Systems – Expanded Contraindications

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56 E. Bell Drive
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Device Description:

Metal-On-Metal Hip prosthesis components provide for total hip replacement with a direct metal to metal articulation. They consist of a series of metal femoral head prostheses (either monolithic or modular) that articulate with highly congruent mating acetabular components without the need for a ceramic or polyethylene liner.

This submission is intended to notify FDA that Biomet has included additional Contraindications to the labeling for Metal-On-Metal total hip prosthesis components to assure the safe and effective use of Biomet Metal-On-Metal components for the appropriate patient populations. These changes are incorporated into one IFU that will be applicable for all Metal-On-Metal components currently cleared by FDA.

Intended Use:

Biomet Metal-On-Metal Total hip replacement components are intended for either cemented or uncemented use to replace the articulating portions of the hip during total hip arthroplasty.

Indications for Use:

Indications For Use:

1. Noninflammatory degenerative joint disease including osteoarthritis and avascular necrosis.
2. Rheumatoid arthritis.
3. Correction of functional deformity.
4. (a) Revision procedures where other treatment or devices have failed (M2a-Taper™ and M2a-Ringloc™).
   (b) Revision of previously failed total hip arthroplasty (M2a-Magnum™ and M2a-38™).
5. Treatment of non-union, femoral neck fracture, and trochanteric fractures of the proximal femur with head involvement, unmanageable using other techniques.

The components of the M2a-Magnum™ system were also cleared for diastrophic variant, fracture of the pelvis, fused hip, Legg Perthes, slipped capital epiphysis, subcaptial fractures, and traumatic arthritis indications. The M2a-Taper™ Metal-on-Metal Hip Joint Replacement Prosthesis are intended for use in cemented and non-cemented primary and revision hip joint arthroplastic procedures.

Summary of Technologies:

The technological characteristics are the same as those included in the predicate Metal-On-Metal 510(k)s already cleared for marketing.

Non-Clinical Testing:

Non-Clinical mechanical testing is not included to support a substantial equivalence determination since this submission is intended only to update labeling for previously cleared medical devices.

Clinical Testing:

Clinical testing is not included to support a substantial equivalence determination since this submission is intended only to update labeling for previously cleared medical devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

MAY 18 2012

Biomet Manufacturing Corp.
% Mr. Gary Baker
56 East Bell Drive
P.O. Box 587
Warsaw, Indiana 46581-0587

Re: K113271
Trade/Device Name: Metal-on-Metal Hip Systems
Regulation Number: 21 CFR 888.3330
Regulation Name: Hip joint metal/metal semi-constrained, with an uncemented acetabular component, prosthesis
Regulatory Class: Class III
Product Code: KWA, LPH
Dated: May 14, 2012
Received: May 16, 2012

Dear Mr. Baker:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic,
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K113271

Device Name: Biomet Metal-On-Metal Total Hip Replacement

Indications For Use:

1. Noninflammatory degenerative joint disease including osteoarthritis and avascular necrosis.
2. Rheumatoid arthritis.
3. Correction of functional deformity.
4. (a) Revision procedures where other treatment or devices have failed (M2a-Taper™ and M2a-Ringloc™).
   (b) Revision of previously failed total hip arthroplasty (M2a-Magnum™ and M2a-38™).
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Prescription Use X	AND/OR	Over-The-Counter Use NO
(Part 21 CFR 801 Subpart D)		(21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Mark N Milhous

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K113271